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<b>Controlled Drug Procedures</b>	<b>ACA Standards:</b> 5-6A-4359M, 5-6A-4346, 5-6A-4377, 5-6A-4378M, 5-6A-4379, 5-6C-4402M, 5-6D-4410M, 5-6D-4413, 4-ACRS-4C-12, 4-ACRS-4C-13, 4-ACRS-4C-17		
<b>Joel McCurdy, M.D, Chief Medical Officer Oklahoma Department of Corrections</b>		<b>Signature on File</b>	

## Controlled Drug Procedures

This procedure will define a process for the control and accountability of controlled drugs distributed and administered by health care providers and qualified health care professionals (QHCP) to inmates of the Oklahoma Department of Corrections (ODOC).

### I. General

The Drug Enforcement Administration (DEA) requires that drugs designated as controlled dangerous substances (CDS) have specific accountability and control procedures in place, over and beyond those required for all other classes of drugs, to ensure proper ordering, dispensing, administration, and destruction. CDS are classified into five schedules (Schedules I – V), with Schedule I being comprised of drugs that are not available for medical use in the United States (e.g., heroin). Schedule II-V drugs, which are available for medical use, are categorized by their potential for abuse and/or dependence, with Schedule II drugs having the strongest potential (e.g., cocaine) and Schedule V drugs (e.g., Lomotil®) having the least.

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All ODOC processes and procedures regarding the control and accountability of CDS are in compliance with state and federal regulatory agencies, including the federal Drug Enforcement Administration (DEA); the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD); Laws and Rules Pertaining to the Practice of Pharmacy (Oklahoma Statutes, Title 59, Chapter 8 and the Oklahoma Administrative Code Title 535 and Appendixes) enforced by the Oklahoma State Board of Pharmacy; and, policies and procedures promulgated by the Oklahoma Department of Corrections. Legal penalties for deliberate mismanagement of CDS are severe for health care professionals, including potential loss of professional license, fines, and imprisonment.

These procedures for the control and accountability of controlled drugs are intended to supplement the policies and procedures for drugs as presented in [OP 140130](#), entitled “Pharmacy Operations.” Detailed procedures and forms regarding the accountability and control of controlled drugs are found in the contract pharmacy provider “spiral bound controlled drug records.”

## II. Characteristics of Effective System Controls

No system of control and accountability for CDS is infallible, but an effective system will have the following characteristics:

- A. Well-defined, not necessarily simple
- B. Comprehensive – ordering, purchase, receipt, administration, destruction, transfer, inventory, documentation, and recordkeeping
- C. High Degree of Accountability and Control – balancing efficiency and effectiveness with distribution and reconciliation
- D. Limited Access – only authorized QHCPs have access
- E. Red Flag Alerts – knowing when something is wrong

## III. Ordering

Each facility will designate a **health care provider of record** to the contract pharmacy that takes the responsibility for the accountability and control of controlled drugs ordered at the facility.

**Patient-specific** controlled pharmaceuticals will be ordered on the “Controlled Drug Prescription Form” ([DOC 140130F](#)).

**Stock** controlled pharmaceuticals will be ordered on the “Controlled Drug Stock Order Form Schedules III-V Only” ([DOC 140130G](#)). Schedule II controlled pharmaceuticals for starter stock must be ordered via a “DEA 222” form specific for that DOC facility address (form available from DEA at: <https://apps.deadiversion.usdoj.gov/webforms2/spring/orderFormsLogin?execution=e1s1>).

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The facility CHSA and the health care provider of record are responsible for the control and accountability of controlled stock drugs by determining and re-evaluating the stock level of each controlled stock drug maintained in medical services.

#### IV. Receipt and Storage

Facility QHCPs must segregate, properly document, store and secure CDS on ***the same day they are received*** from the contract pharmacy provider.

The facility health services administrator, or designee, shall be responsible for verification that CDS received from any source are properly recorded in the controlled drug perpetual inventory system.

Secured storage of CDS, syringes, and needles is performed in strict accordance with federal and Oklahoma state regulations, and operational policies approved by ODOC. The control and accountability of these items is maintained by the daily perpetual inventory conducted by CHSA-designated/ approved QHCP.

Community correctional facilities will use "Community Corrections Supervised Medication/Syringe Count Log" ([DOC 140130J](#)) for the control and accountability of CDS issued by correctional officers for inmate self-administration.

Unused or expired CDS must be segregated from viable stock/prescription drugs and stored in a secure area (i.e., under a double lock) until either authorized for credit/return or prepared for REVERSE DISTRIBUTORSHIP destruction as detailed section X of this MSRM. Segregated CDS must still be accounted for on the perpetual count while they remain on-site.

#### V. Administration

All CDS are administered by or under the supervision of a QHCP (e.g., nurse) or issued (as personal property) by a correctional officer for patient self-administration.

#### VI. Wastage

Any wasted dose, partial or full, must be properly documented by a QHCP on the spiral bound controlled drug records, with a separate ODOC employee (e.g., Pharmacy Director, correctional officer) bearing witness by signature. Single, wasted CDS doses may be disposed of via an ODOC-approved drug-disposal system. Wasted doses of medications may NOT be disposed of by running water in sink or toilets or by placement in sharps containers.

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## VII. Accountability and Control

### A. Perpetual Counts

1. Each Schedule II, III, IV, and V controlled ***patient-specific*** medication stored within the facility will be accounted for on a daily perpetual inventory system utilizing the spiral bound controlled drug records
2. Each Schedule II, III, IV, and V ***stock*** controlled medication stored within the facility will be accounted for on a daily perpetual inventory system utilizing the spiral bound controlled drug records
3. The facility health services administrator (CHSA), or designee, shall be responsible for verification that CDS received from any source are properly recorded in the controlled drug perpetual inventory system.

### B. Shift Counts

1. Inventory counts of CDS (including expired or unused controlled drugs) will be conducted by two QHCPs at the beginning and end of each shift using spiral bound book controlled drug Shift Count records.
2. For instances when only one QHCP is onsite, one signature is acceptable for the shift count.
3. This procedure only applies to ODOC HOST facilities, and does not include correctional officer witnessed inmate self-administration of drugs; those procedures are detailed in [MSRM 140143-02](#) entitled, "Correctional Officer Observation of Inmate Self-Administered Medication and Issuance Procedure."

### C. Discrepancies.

1. All on duty staff who are authorized to access CDS (QHCPs and health care providers) are required to stay on duty until counts are accurate and correct or cleared by security to leave the facility in the event that a discrepancy is unresolved. See section VIII of this procedure for more information.

D. Community correctional facilities will use "Community Corrections Supervised Medication/Syringe Count Log" ([DOC 140130J](#)) for the control and accountability of controlled drugs.

E. Notations must be made to indicate days when the medical services unit is closed by noting "**Closed**" on the count sheet.

F. Health care providers are responsible for the control and accountability of CDS by determining and re-evaluating the stock level of each controlled stock drug maintained in medical services.

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## VIII. Unresolved Discrepancies

Unresolved discrepancies must be verbally reported by the discovering party to the facility security shift supervisor and the CHSA within one hour of discovery. The time of discovery shall be defined as that time at which a suspected discrepancy is confirmed by search or documentation and shall not exceed 2 hours from when initially suspected. ODOC Chief Medical Officer, or his designee will be notified by the CHSA of unresolved discrepancies within four (4) hours of discovery. An "Incident/Staff Report" ([Attachment A](#), [OP-050109](#)) must be completed by the CHSA.

A "Serious Incident Report" ([Attachment H](#), [OP-050108](#)) may be completed by the facility head, or designee, if warranted.

## IX. Theft or Loss of Controlled Substances

Theft or loss of CDS is defined as an unresolved discrepancy after eight (8) hours of discovery and must be reported to the deputy director of Treatment and Rehabilitation Services, or his designee. Internal Affairs will be contacted by the deputy director, or his designee to conduct an investigation of the alleged theft or loss of the CDS. The Oklahoma Department of Corrections Chief Medical Officer, or his designee following the investigation and written recommendation of Oklahoma Department of Corrections Internal Affairs may report suspected theft or loss to the Drug Enforcement Administration. Known theft, significant loss, and losses in transit must be reported to the DEA within one business day. The applicable DEA Registrant must report known theft, significant loss, or losses in transit on DEA Form 106 (located at: <https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp>).

An "Incident/Staff Report" ([Attachment A](#), [OP-050109](#)) as well as a "Serious Incident Report" ([Attachment H](#), [OP-050108](#)) must be completed by the facility head, or designee.

## X. Destruction of Expired or Unused Controlled Drugs

Other than the wastage of partial or full, refused, contaminated doses of CDS via approved drug disposal systems, the destruction of controlled drugs on site at the facility is NOT permitted. ALL destruction of controlled drugs must be done by reverse distribution, with proper documentation of such transactions on REVERSE DISTRIBUTORSHIP forms, and the CDS must be sent to the address specified on the form. The initial copy will be supplied to each medical unit by the contract pharmacy provider (or its contracted reverse distributor) and will be the responsibility of the CHSA to keep the forms available on the unit at all times.

All spiral bound controlled drug records must be complete and document doses that have been transferred to the REVERSE DISTRIBUTORSHIP forms for destruction.

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Drugs to be surrendered to REVERSE DISTRIBUTORSHIP for destruction must be processed with proper forms and promptly sent out via REVERSE DISTRIBUTORSHIP as soon as possible (within 14 days). It is the CHSA's responsibility to assure that controlled drugs intended for destruction are not stockpiled but processed promptly.

All forms (DOC, DEA, REVERSE DISTRIBUTORSHIP) relating to the proper control and accountability of CDS must be kept on file for a minimum of FIVE (5) years. Destruction records of controlled drugs should be segregated from other controlled drug records.

## XI. Credits

In general, credits for CDS are not permitted and are done only if authorized by the contract pharmacy provider.

## XII. Transfer of Medications

Controlled drugs can be transferred per [OP-140113](#) entitled "Health Assessment for Inmate Transfers", with proper notations in the spiral bound controlled drug records, as follows:

- A. All inmates transported, regardless of destination, will be transported with their packaged, prescribed medications, including insulin. It is the responsibility of the applicable DEA Registrant or designee (i.e., the transferring facility) to ensure that any/all CDS transferred with an inmate reach the intended site in entirety. Proper documentation of the CDS transfer must be obtained, stored, and retained in compliance with CDS record-keeping regulations (i.e., get a receipt from the site to which the CDS is sent).
  1. Medications that are administered at pill line including CDS will be sealed in a manila envelope with the inmates' name and DOC number and placed in the inmate medical record or attached to the "Medical Transfer Summary" ([DOC 140113A](#)). The prepared medication package will be issued to transporting personnel prior to departure and will be stored appropriately where accessible to the transporting officers.
  2. Inmate access to and possession of prescription pharmaceuticals during transportation will be limited to keep-on-person (KOP) medications of respiratory inhalers, nitroglycerine sublingual tablets or any medications the healthcare provider/ QHCP determines to be medically necessary. All other KOP medications will be stored with the inmate's personal property.

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- B. Medications that are CDS that are specially dispensed for the inmate and as defined by federal law will be transferred as described in Section III. C. item 2 of [OP-140113](#) entitled "Health Assessment for Inmate Transfers."
- C. Inmates transferred for a Sheriff's Office Writ will be sent with an adequate supply of medications to cover their estimated time to be spent at the county jail. The medications shall be clearly labeled with the inmates' name, dose, route and frequency. Any medications and or medical care required after the initial supply sent by DOC is exhausted will be at the expense of the county.
- D. When an inmate comes from a county jail CTU will return medication supplies to DOC medical personnel at the receiving facility per [OP-040401](#) entitled "Transportation of Inmates by Central Transport Unit (CTU)".

### XIII. Records

By Oklahoma law, all records for CDS (see listing below) must be kept for a period of five (5) years. These records should be filed and maintained by the facility CHSA in a secure location with limited access. Records to be filed include the following:

- a. Completed spiral bound controlled drug records
- b. Completed destruction logs (REVERSE DISTRIBUTORSHIP)
- c. Completed shift count logs
- d. DEA records (DEA 222, DEA 106)
- e. Pharmacy licenses
- f. Pharmacy invoices
- g. Pedigrees
- h. Inventory/audit records

### XIV. References

OP-140113 entitled "Health Assessment for Inmate Transfers"

OP-140130 entitled "Pharmacy Operations"

DEA Forms at

<https://apps.deadiversion.usdoj.gov/webforms2/spring/orderFormsLogin?execution=e2s1>

Spiral bound controlled drug records

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## XV. Action

The chief medical officer, Medical Services will be responsible for compliance with this procedure.

The chief medical officer, Medical Services will be responsible for the annual review and revisions.

Any exceptions to this procedure will require prior written approval from the director.

This procedure will be effective as indicated.

Replaced: Medical Services Resource Manual 140130-03 entitled "Controlled Drug Procedures" dated January 28, 2016.

Distribution: Medical Services Resource Manual

Referenced Forms	Title	Location
DEA 106	"Report of Theft or Loss"	<a href="#">DEA Weblink</a>
DEA 222	"Schedule II Order Form"	<a href="#">DEA Weblink</a>
<a href="#">Attachment H</a>	"Serious Incident Report"	<a href="#">OP 050108</a>
<a href="#">Attachment A</a>	"Incident/Staff Report"	<a href="#">OP 050109</a>
<a href="#">DOC 140113A</a>	"Medical Transfer Summary"	<a href="#">OP 140113</a>
<a href="#">DOC 140130F</a>	"Controlled Drug Prescription Form"	<a href="#">OP 140130</a>
<a href="#">DOC 140130G</a>	"Controlled Drug Stock Order Form Schedules III-V Only"	<a href="#">OP 140130</a>
<a href="#">DOC 140130J</a>	"Community Corrections Supervised Medication/ Syringe Count Log"	<a href="#">OP 140130</a>